LIMITED WARRANTY

This warranty is in lieu of all other warranties, expressed or implied.

In the U.S.A., Nicolet Vascular warrants this **Elite™** against defects in materials or workmanship as follows:

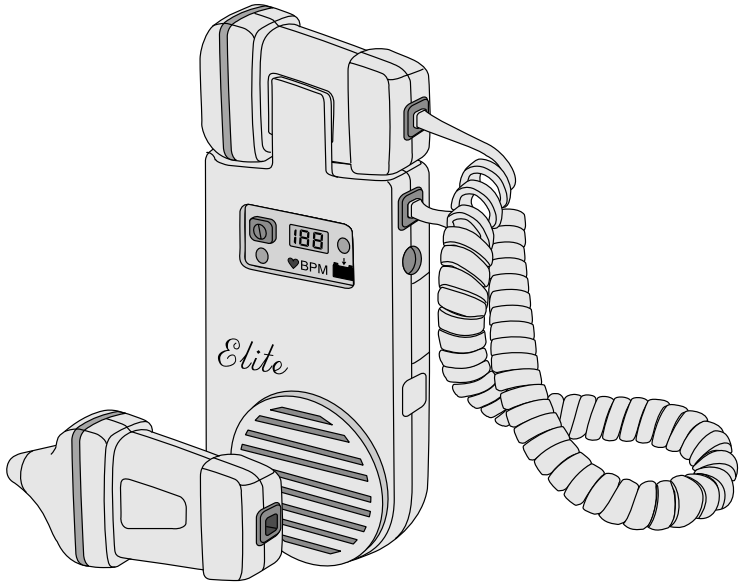
Parts – Nicolet will repair or replace parts for a period of five (5) years after date of original purchase with no charge. Nicolet reserves the right to determine whether a unit should be repaired, replaced or exchanged.

Labor – Nicolet will repair, replace or exchange the **Elite** with no labor charge for a period of one (1) year after date of original shipment when it is shipped to an authorized service center. Transportation and insurance to the service center are to be prepaid by the purchaser. This applies to units shipped to the U.S. and Canada only.

Limitations – This product is to be used for the intended and labeled indications presented in this manual. This warranty shall not apply to any products repaired or altered by anyone not authorized in writing by Nicolet. Nicolet makes no warranty of the results to be obtained. Nicolet's sole responsibility shall be to replace, exchange or repair this product under the terms stated above and does not cover loss or damage from external causes such as, but not limited to, weather, theft or abuse. **This warranty does not apply to batteries, shipping case or other accessories, or to damage from shipping, tampering, misuse or negligence.** Preventative maintenance, the refinishing or replacement of any cosmetic defect or deterioration, or the replacement of batteries unless damaged by a component failure, is not covered by this warranty. Nicolet will not be responsible for any loss, damage or injury resulting from delay in rendering service under this warranty. NICOLET SHALL NOT BE RESPONSIBLE FOR ANY SECONDARY CHARGES OR CONSEQUENTIAL DAMAGES FROM ANY BREACH OF ANY WARRANTY, EXPRESSED OR IMPLIED. Since some states do not allow the exclusion or limitation of consequential damages, some of this limitation may not apply to you. This warranty gives you specific legal rights which vary from state to state.

Nicolet *Elite*™

User's Manual



Nicolet
VASCULAR
a division of VIASYS Healthcare

Congratulations on your choice of the Nicolet Elite™

from Nicolet Vascular

The **Elite** provides the features which have made Nicolet Vascular a world leader in Doppler technology: reliability, quality, sensitivity and value.

⚠ CAUTION: Federal law (USA) restricts this device to use by or on the order of a physician.

Nicolet Vascular strives for continuous improvement. Please contact us if you have comments or suggestions for improvements regarding our products or services.

CE 0344

The CE 0344 Mark identifies compliance with the Medical Device Directive 93/42/EEC.

Nicolet Vascular - a division of VIASYS Healthcare
5225 Verona Rd., Bldg. 2
Madison, WI 53711-4495
Phone: 608-441-2266
(800) 525-2519
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E-mail: info@NicoletVascular.com
www.NicoletVascular.com

European Authorized Representative:
VIASYS Healthcare
Welton Road
Warwick, CV345PZ U.K.

M7-0775 Rev. H

Inaccurate fetal heart rate display (**Elite** 200, 200R).	a. The detected signal is maternal or maternal mixed with fetal sounds. A maternal sound, usually one half of the fetal sound, may produce harmonics which are in the fetal range. Reposition the probe to detect only fetal sounds. b. Excessive static. Some probe movement patterns may cause erroneous heart rate displays. Refer to the above section on static for recommendations. c. Fetal heart rate is out of the display range. Harmonicsmaycause doubling of the displayed fetal heart rate.
Audible hum or feedback with no signal present.	a. Replace or recharge battery.

Service

Service information and assistance is available on the **Elite™** by phoning Nicolet Vascular at (800) 525-2519, or (608) 441-2266. Fax (608) 441-2242 or visit our web site at www.nicoletvascular.com.

If you need to return the unit for repair, contact Nicolet Vascular Technical Service first to obtain a Repair Authorization # (RMA). Package the product carefully (in its original container, if possible) and send it to:

Attn: Service Department
Nicolet Vascular
2920 Commerce Park Drive
Madison, WI 53719

Ship the product, insured, via US mail or United Parcel Service.

Include a note indicating the problem, the name of a contact person and their phone number.

For service outside of the United States, please contact the local representative from whom you purchased the unit.

Warranty: It is important that you return the warranty card supplied with your **Elite** as soon as possible. The specific warranty conditions and limitations were sent with your system. Your **Elite** is protected by a limited warranty.

Accessories

Description	Catalog Number	Description	Catalog Number
2 MHz OB Probe	N200	Walkman-style Headset	A210
3 MHz OB Probe	N300	Soft-sided Padded Carrying Case	A420
5 MHz Vascular Probe	N500	9 Volt Alkaline Battery (**Elite** 100; **Elite** 200)	C623
8 MHz Vascular Probe	N800	9 Volt NiMH Battery (**Elite** 100R; **Elite** 200R)	C622
2 MHz Waterproof OB Probe	NW20	Replacement Recharger (**Elite** 100R; **Elite** 200R)	C640
12 2 oz. Ultrasound Gel Tubes	A100		
12 0.25 liter Ultrasound Gel Bottles	A120		

Main unit recharge light does not come on (**Elite** 100R, 200R).	a. Verify that the wall transformer is plugged in and that the wall outlet has power.
	b. Verify that the cable from the wall transformer is plugged into the unit.
Main unit is on, but no audio signal is present (All Models).	a. Headphones interrupt the internal speakers, remove the headphones.
	b. Probe is not plugged in.
Static (All Models).	a. Use an ample supply of ultrasonic coupling gel. Hold the probe steady once a signal has been detected.
	b. Some coupling agents, such as baby oil, maycause extra static.
	c. Reduce the volume level.
Weak or no fetal signal detected (All Models).	a. Fetus is too young. Wait a few weeks before trying the test again.
	b. Use plenty of coupling gel.
	c. Try turning up the volume.
Weak or no blood flow signal detected (All Models).	a. Use plenty of coupling gel. b. Try turning up the volume.
	c. If using 8MHz vascular probe, adjust angle of probe to optimize signal.
No fetal heart rate displayed with audible tones (**Elite** 200, 200R).	a. Fetal heart rate is outside of display range. See Specifications Section.
	b. The detected signal is blood flow or placental flow. The characteristics of placental flow sounds produce a smooth Doppler envelope. A very smooth envelope will not correlate well, so no rate is displayed. Reposition the probe.
No vascular heart rate is displayed with audible tones (**Elite** 200, 200R).	a. Heart rate range is outside of display range. See Specifications Section.
Unit shuts off during use. (**Elite** 200, 200R)	a. The unit shuts off after approximately 3 minutes if not in use. Large signals are used to reset the power-off-timer. Faint signals may not reset the timer.
(All Models)	b. Battery is low. Replace or recharge.
Inaccurate vascular heart rate (**Elite** 200, 200R).	a. Certain flow waveforms contain large display display harmonics which can cause heart rate doubling.
Unstable fetal heart rate display (**Elite** 200, 200R).	a. Fetus is too young. Wait a few weeks before trying the test trying the test again, or try a manual method for determining heart rate.
	b. Fetus is moving. Wait a few minutes to see if the fetus settles down.
	c. Excessive static. Some probe movement patterns may cause erroneous heart rate displays. Refer to the above section on static for recommendations.
	d. Probe is detecting blood flow sounds. Reposition the probe.

TABLE OF CONTENTS

The purpose of this manual is to guide the user in the operation and care of the **Elite**. Every reasonable effort has been made to present accurate information. Nicolet Vascular hereby disclaims and makes no warranty with respect to any diagnosis, clinical condition or interpretation made based on the information presented herein. Refer to the Limited Warranty at the end of this manual for the equipment warranty.

⚠ **Caution:** The 5 MHz and 8MHz vascular probes are not intended for fetal use.

⚠ **Warning:** This product is not intended for use on or around the eyes. This product is not intended for use on non-intact skin.

LIMITATIONS

The theory of Doppler ultrasound is beyond the scope of this manual, but is covered in many recent publications. The **Elite** is designed to be reliable, but as with all medical instruments, should be treated with care. While the **Elite** augments the user's skills, it is not a substitute for medical training and knowledge.

NOTE: The **Elite** provides the listener with information about the fetus and vascular conditions. Under poor signal conditions, the fetal heart sounds and readings may not be accurate. (Refer to the Troubleshooting section at the end of this manual for a description of sensitivity problems and solutions.) If there is any doubt about the fetal condition after using the Doppler, further investigation should be initiated immediately.

PRODUCT DESCRIPTION

The **Elite** is a non-invasive hand-held Doppler with a speaker. The **Elite** has the following special features that will enhance your product use:

On/Off: ⏻

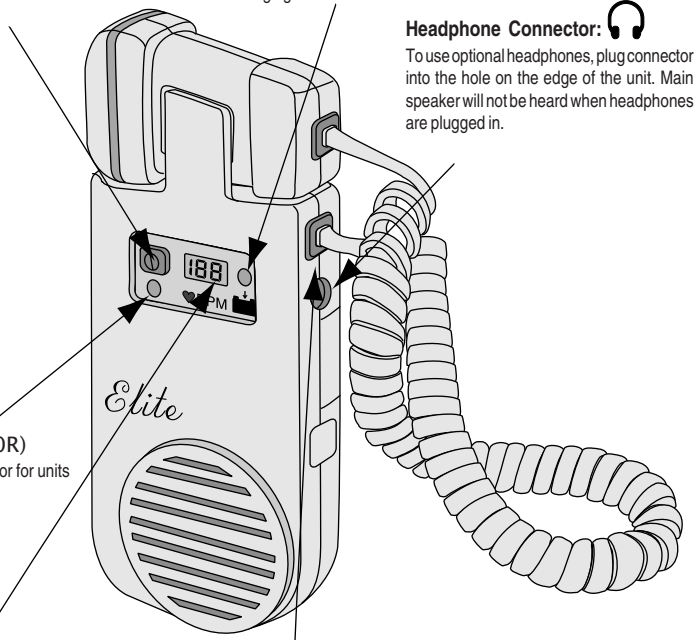
Pressing the **On/Off** button on the front panel of the unit turns on the **Elite**. The **Elite** is turned off by again pressing the **On/Off** button.

Recharge Indicator:
(**Elite** 100R & 200R)

The green light turns on to indicate that the unit is recharging.

Headphone Connector:

To use optional headphones, plug connector into the hole on the edge of the unit. Main speaker will not be heard when headphones are plugged in.



On Indicator:
(**Elite** 100 & 100R)

Green LED "On" indicator for units without display.

Heart Rate/Low Battery Indicator (**Elite** 200 & 200R): ♥

The digital display shows heart rate. The display flashes when batteries are low.

Probe Connector:

Disconnect the probe by holding the probe in one hand, grasping the connector at the bottom of the probe in the other hand, firmly depressing the clear tab on the connector, and pulling the connector from the probe.

Warning

THE Elite IS NOT EXPLOSION PROOF. DO NOT USE THE Elite OR PROBES IN THE PRESENCE OF FLAMMABLE OR EXPLOSIVE GASES. DO NOT IMMERSE THE UNIT OR PROBES IN FLUIDS AND DO NOT AUTOCLAVE.

Acoustic Output Reporting Table

Transducer Model: **Elite** ™ 8MHz **Operating Mode:** Continuous Wave (cw)

Application(s): Peripheral Vascular

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global **Maximum** Value			.033	348	.348
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	.074		
	W_0	(mW)		5.2	5.2
	f_c	(MHz)	7.8	7.8	7.8
	Z_{sp}	(cm)	0.52	0.52	0.52
	Beam dimensions	x_{-6} (cm)		0.32	0.32
		y_{-6} (cm)		0.17	0.17
	EBD	Az. (cm)		0.20	
		Ele. (cm)		0.46	

When in the presence of audible interference the heart rate display may be inaccurate.

$I_{SPTA.3}$ - **The derated spatial-peak, temporal-average intensity** (milliwatts per square centimeter).
$I_{SPPA.3}$ - **The derated spatial-peak, pulse-average intensity** (milliwatts per square centimeter).
MI - **The Mechanical Index.**
$p_{r.3}$ - **The peak rarefactional pressure** (megapascals) associated with the transmit pattern giving rise to the value reported under MI.
W_0 - The total time-average **ultrasonic power** (milliwatts).
f_c - The probe **center frequency** (MHz).
z_{sp} - The axial distance at which the reported parameter is measured (centimeters).
x_{-6} & y_{-6} - The -6dB beam dimensions in the x-y plane where z_{sp} is found (centimeters).
EBD - the **entrance beam dimensions** (centimeters). These dimensions are the same as the dimensions of the transmit crystal.

Operating Conditions:
There are no user controls which affect the ultrasound output.

Measurement Uncertainties:
Power: +29%, -42%
Pressure: +17%, -23%
Intensity: +18%, -29%
Frequency: +1%, -1%

Additional Information for IEC-1157
The output beam intensity I_{ob}=48 mW/cm²
This transducer is intended for direct patient contact.

The probe face has a liquid ingress level of IPX4.

Troubleshooting Elite Problems

Problem:	Solution:
Unit will not turn on (All Models).	a. Battery is discharged. Replace battery or recharge for several hours before use. b. Unit does not operate while recharging, remove from the recharger.
Power LED flashes (**Elite** 100, 100R). Heart rate display flashes (**Elite** 200, 200R)	a. Main unit battery is low and should be replaced or recharged.

Ultrasound Output:

Acoustic Output Reporting Table

Transducer Model: Elite™ 2MHz **Operating Mode:** Continuous Wave (cw)
Application(s): Continuous Fetal Heart Monitoring

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global **Maximum** Value			.031	42.6	.043
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	.043		
	W_0	(mW)		13.6	13.6
	f_c	(MHz)	2.0	2.0	2.0
	Z_{sp}	(cm)	1.62	1.62	1.62
	Beam dimensions	x_{-6} (cm)		0.8	0.8
		y_{-6} (cm)		0.4	0.4
	EBD	Az. (cm)		0.79	
		Ele. (cm)		1.58	

Acoustic Output Reporting Table

Transducer Model: Elite™ 3MHz **Operating Mode:** Continuous Wave (cw)
Application(s): Continuous Fetal Heart Monitoring

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global **Maximum** Value			.028	55.4	.055
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	.116		
	W_0	(mW)		20.0	20.0
	f_c	(MHz)	3.04	3.04	3.04
	Z_{sp}	(cm)	0.9	0.9	0.9
	Beam dimensions	x_{-6} (cm)		1.01	1.01
		y_{-6} (cm)		0.85	0.85
	EBD	Az. (cm)		1.02	
		Ele. (cm)		1.40	

Acoustic Output Reporting Table

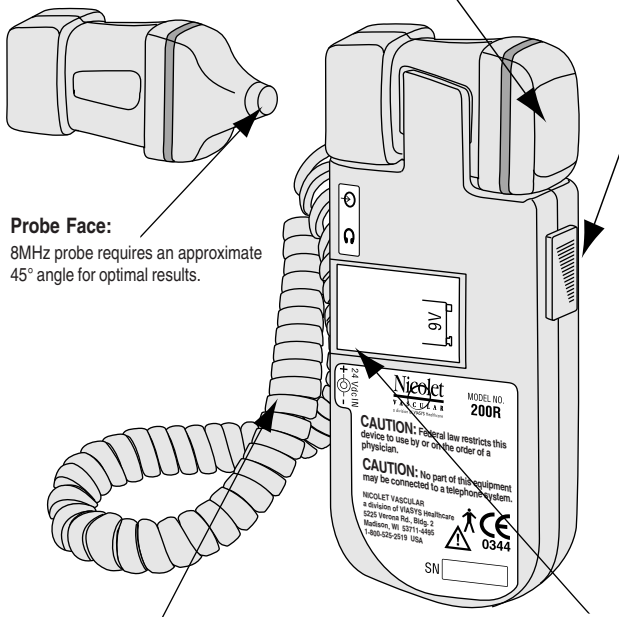
Transducer Model: Elite™ 5MHz **Operating Mode:** Continuous Wave (cw)
Application(s): Peripheral Vascular

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global **Maximum** Value			.029	114.7	.114
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	.068		
	W_0	(mW)		35.0	35.0
	f_c	(MHz)	5.45	5.45	5.45
	Z_{sp}	(cm)	0.4	0.4	0.4
	Beam dimensions	x_{-6} (cm)		1.13	1.13
		y_{-6} (cm)		0.34	0.34
	EBD	Az. (cm)		0.46	
		Ele. (cm)		1.24	

Probe Face:
Place 2 MHz, 3 MHz or 5 MHz probe flat on skin. There is no need to tip at various angles to detect fetal heartbeat or blood flow in artery or vein.

Louder

Volume control:
Volume is adjusted by sliding the "Volume" control button on the side of the unit. Slide the button up to make the sound louder. Slide the button down to make the sound quieter.



Probe Face:
8MHz probe requires an approximate 45° angle for optimal results.

Battery Replacement: 9V
To replace a battery, remove the battery compartment door and remove the old battery. Carefully install the new battery with the connector end as shown on the label. Replace the battery compartment door.

Recharger 24 Vdc IN **(Elite 100R & 200R):**
Transformer/recharger unit plugs into main unit for recharging rechargeable batteries. The unit will not operate while the recharger is plugged in.

Warning

USE ONLY RECHARGER AND RECHARGEABLE BATTERIES AS SPECIFIED BY NICOLET VASCULAR. USE OF OTHER BATTERIES MAY CREATE A HAZARDOUS SITUATION AND VOID THE MANUFACTURERS WARRANTY.

SAFETY OF ULTRASOUND

The American Institute of Ultrasound in Medicine (AIUM) has addressed the concerns relating to the safety of ultrasound and has issued the following statement as of March 1993:

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the AIUM herein addresses the clinical safety of such use:

"No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present."

Nicolet Vascular's policy is to always use as low an ultrasound power as practical. The level of ultrasound power emitted by the **Elite** is not adjustable. Prudent use on the operator's part would include minimizing the length of time that the patient is undergoing the ultrasound exposure.

CONTRAINDICATIONS

The Elite is not for invasive use, not for use near or on non-intact skin and not for use near the eyes. The Elite 5 MHz and 8 MHz probes are not intended for fetal use.

OPERATION

Remove the probe from the main unit by grasping the probe and pulling it straight up and away from the unit. Turn on the unit by pressing the **On/Off** button. All sections of the liquid crystal display (**Elite** 200 and 200R) will illuminate to ensure they are working properly.

1. Make sure the probe cable is connected at both the probe and the main unit.
2. Apply gel to the face of the probe and begin the Doppler examination.
3. Adjust the volume on the main unit as needed, by sliding the slider up to increase the volume or down to decrease the volume.
4. When finished with the exam, turn the unit off by pressing the **On/Off** button.
5. Refer to cleaning instructions to clean the probe.

Note: Only sterilize the probe with these methods. Do not sterilize the main unit in this manner.

Battery
Remove battery if the **Elite** will not be in use for an extended period. Do not expose to temperatures greater than 65°C (149°F).

Transport and Storage

Temperature:	-20°C to 60°C
Humidity:	15% to 90% (non-condensing)
Pressure:	500 hPa to 1060 hPa

Product Compatibility

The **Elite** was not designed to be compatible with other products. Nicolet Vascular recommends using only Nicolet Vascular-brand accessories that have been approved for use with the **Elite**.

Warning: No part of the Elite is to be connected to a telephone system.

SPECIFICATIONS

Dimensions:		17cm x 7.5cm x 2.5cm (6.8" x 2.9" x 1.0")
Weight (with one probe):		Approximately 0.25 kg (.60 lb.)
Doppler Technology:		Continuous Wave (CW) Unfocused.
Battery Type:		9 volt alkaline or 9 volt rechargeable [IEC #6LR61 or NEMA # 1604A]
Operational Temperature:		10 to 32 degrees C (50 to 90 degrees F)
Speaker:		2.25", 8 Ohms
Audio Output:		1/4 watt typical
Headphones:		8 Ohms, mono 3.5mm
Frequency Response:		-3dB @ 360 Hz and 1.2 K for **Elite** 100 Series
		-3dB @ 391 Hz and 1.2 K for **Elite** 200 Series
Safety Standards:		IEC 601-1 and IEC601-1-2 (if applicable and only when using the appropriate recharger)
Classification:		Internally Powered Equipment, Type B
Display Rate (BPM):		60-119 ± 2 for Vascular Probe
(If applicable)		60-199 ± 2 for OB Probe
Recharger:	**Input:**	120 VAC 60 Hz (PN: PS-0019)
		or
		240VAC 50Hz @ 6VA (PN: PS-0028)
	Output:	24VDC @ 65ma

Angling. The 2 MHz, 3 MHz and 5 MHz probes are designed to achieve optimum results without angling - lay the probe face down against the skin. The 8 MHz probe requires an approximate 45° angle for optimum results.

Carrying the unit. Always check the probe to make sure it is completely seated in the holding clips. Never presume the probe is lodged tightly.

Care of the Instrument

Main Unit

Keep the instrument clean by wiping it periodically with a damp cloth and mild disinfectant cleaner. DO NOT immerse in fluids or use solvent cleaners.

Doppler Probes

Caution: DO NOT USE organic cleaning agents or alcohol. DO NOT immerse the probes in liquid.

Note: The following steps are recommended for the cleaning and disinfecting of Nicolet Vascular probes before each use. The procedure renders clean probes which are neither sterile nor pyrogen free. When carried out according to standard clinical practice, it should help prevent the transfer of infectious agents, through the elimination of significant microbiological contamination between uses.

The probe should be wiped clean with a soft non-abrasive cloth or disposable wipe soaked in an aqueous disinfectant. Avoid aerosol preparations of disinfecting agents, since they may contain alcohol or organic solvents.

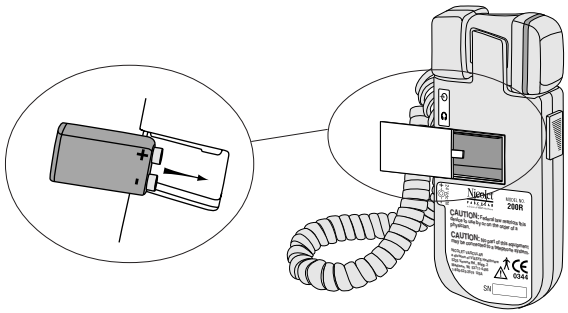
The probe should then be wiped with a non-abrasive cloth moistened with water.

Clean, dry probes should be packaged in clean bags, covered trays, or other suitable systems for storage and transport.

If sterilization of the probes is desired, it can be done with cold gas sterilization (such as ethylene oxide at less than 140° F), or the Sterrad™ System. The user is responsible for verification of sterility. Follow the manufacturer's instruction for your model.

6. To replace the battery, firmly push down on the battery door and slide the door off. Remove the existing battery. To replace with a new battery, align the battery as indicated on the battery door and in the diagram. Replace the battery door by sliding and snapping it in place.
7. To recharge the battery (**Elite**100R & 200R), turn the unit off by pressing the "On/Off" button. Plug a Nicolet authorized recharger into the recharger jack. Verify that the **Recharge** LED lights up.

   Let the unit recharge for a minimum of 14 hours to fully charge the battery.



Warning

Replace batteries with Nicolet Vascular approved types only.

Obstetrical Exams

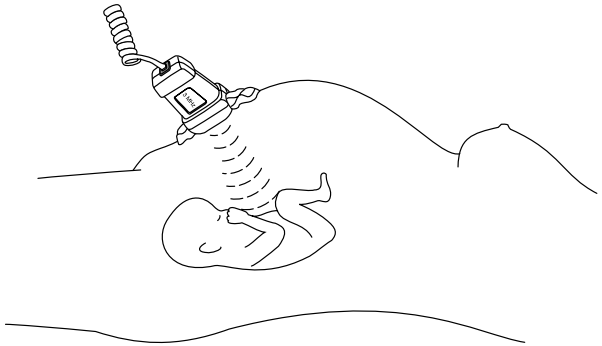
Doppler ultrasound in an obstetrical application is used primarily to reassure the mother of the presence of fetal viability. In some patients the fetal heart can be heard as early as 8 to 12 weeks. It should be audible 95% of the time in 12-week pregnancies and nearly 100% after 14 weeks.

The 3 MHz probe is designed to be used early in pregnancy. The 2 MHz waterproof probe is for use later in pregnancy in larger patients, or for use in water labors and/or deliveries.

The exam is most easily done with the patient supine, although it may also be accomplished in a sitting or standing position. Expose the abdomen and apply a generous amount of coupling gel to the face of the probe. It is important to maintain good coupling at all times with no air bubbles between the probe and the abdomen.

If preferred, start the examination using optional earphones for privacy. The key to the examination is to intercept the fetal heart with the beam from the probe. The beam travels in a relatively straight direction much like a flashlight beam.

In the first trimester, the best technique is to start with the probe on the midline of the abdomen and aimed downward behind the pubic bone. The probe should be moved very slowly to search the most likely areas. Because the fetal heart sounds are faint at this time, be careful not to scan too quickly or the sounds may be missed.



It is often difficult to find the fetal heartbeat during the first trimester and this by itself is not a cause for alarm. A full bladder may make finding the heartbeat a little easier.

The fetal heartbeat sounds like a galloping horse and is about twice the speed of the mother's heart rate. The heart rate will be displayed on units with an LCD display. The placental blood flow sounds more like a whirlwind.

NOTE: The **Elite** provides the listener with information about the fetus; however if there is any doubt about fetal condition after using the Doppler, further investigation must be initiated immediately.

When you have completed the exam, press the **On/Off** button to turn off the **Elite**. Then wipe the gel off the face of the probe. Return the probe to the top of the unit for protection.

Vascular Exams

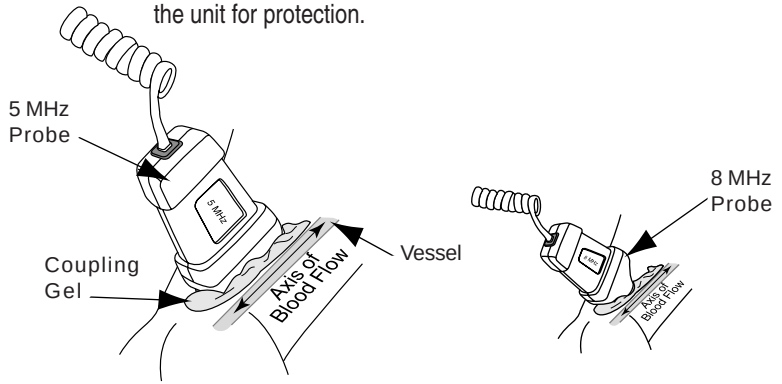
A Doppler is very valuable for locating veins for injections or IVs, obtaining difficult to locate systolic blood pressures or listening to flow within a vessel.

Apply a liberal amount of gel to the vascular probe and gently place it on the skin, aligning it with the vessel. It is not necessary to press hard. If preferred, use optional headphones to eliminate the speaker sounds. If using the 5 MHz broadband probe, no angling of the probe is necessary. When using the 8 MHz probe, use an approximate 45° angle for optimum results.

Arterial sounds pulsate with every heartbeat and venous sounds are spontaneous with respiration. The sound a vein produces is similar to that of a windstorm. Heart rate will be calculated and displayed on units with an LCD display.

These characteristic sounds are easily heard and may be utilized to help distinguish a healthy vessel from a diseased one.

When you have completed the exam, press the **On/Off** button to turn off the **Elite**. Then wipe the gel off the face of the probe. Return the probe to the top of the unit for protection.



GENERAL HINTS

Use plenty of coupling gel. Ultrasound is almost completely stopped by any air or bubbles between the skin and the probe. Use the ultrasound gel liberally for best results.

Move the probe slowly. When searching for the fetal heart, a slow rocking and rotating motion will minimize noise and help avoid missing the heartbeat. Rest your hand on the patient to stabilize the probe and to avoid unwanted motion and noise.

Maintain probe contact. It is important to keep the entire probe face in contact with the skin surface. Holding the probe in this manner allows you to obtain the best possible sounds.